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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,337	04/19/2004	Jorg Senn-Bilfinger	25079Y	9566

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EXAMINER	
RAHMANI, NILOOFAR	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,337	SENN-BILFINGER ET AL.	
	Examiner	Art Unit	
	Niloofar Rahmani	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/182,619.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The office action of 12/07/2005 has been vacated. Claims 1-14 are currently pending in the instant application.

Priority

2. This application is a 371 of PCT/EP01/03514, filed on 03/28/2001, which claims the priority of EP 00106695, filed on 03/29/2000. The priority document, however, is not in the file.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

3. *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are rejected because the definition for R4' and R5' is vague and unclear. What groups are encompassed by the "radical from which a hydroxyl group is formed under physiological conditions"? It is recommended that the chemical names or structures be recited in the compound claim.

Claims 2-7 are rejected because –OR' has no antecedent basis in the base claim 1. Inclusion in claim 1 is recommended.

Claims 10, and 14 are rejected because the term " gastrointestinal illnesses" is vague and indefinite. Correction is required.

Claims 4, 6-7 are rejected because of double dependency. For example, does claim 4 depend on claim 2 or 3? Correction is required.

Claims 9, 13 are rejected because the claims are self-conflicting. Pharmaceutical compositions by definition must be effective yet non-toxic. Claims 9, 13 are pharmaceutical compositions without dosage limitation i.e. included both ineffective and toxic amount. It is recommended that "therapeutically effective amount" be incorporated in the claims.

4. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-7, 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-4, 6-7, 9-14 lacks description of the claims i.e. " hydrate". Hydrate is unpredictable because there are different hydrates. There are

½ hydrate, 3 hydrates, or ¾ hydrate, etc. Therefore, the specification lacks description of "hydrate of them".

5. *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims.
2) The nature of the invention,
3) The state of the prior art,
4) The level of one of ordinary skill,
5) The level of predictability in the art,
6) The amount of direction provided by the inventor,
7) The existence of working examples,
8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to tricyclic imidazo [1,2-a] pyridines for treating or preventing gastrointestinal illnesses. The compounds taught to treat acid secretion (see page 46 of specification). On page 43 of specification describes gastrointestinal illnesses as being caused by acid levels i.e. (medicaments, chemicals, gastric acid or stress) or microorganisms and bacterial toxins. Specification does not provide for treating gastrointestinal illnesses caused by microorganism or bacterial toxins. The specification, while providing enablement for treating gastrointestinal illnesses of acid level origin does not provide of treating gastrointestinal illnesses of microorganisms or bacterial toxins.

The state of the prior art: Proton pump inhibitors (PPIs) derivatives are known (Messaouik D., International Journal of Pharmaceutics, vol. 299, pages 65-72). Certain PPIs (omeprazole, lanzoprazole and esomeprazole) compounds have been shown for treating stress-induced ulcers, which caused by acid level in stomach.

Helicobacter pylori is one of the most prevalent microorganisms is a major cause of gastrointestinal disease in human (Chang-Young Lim, Journal of Clinical Microbiology, pages 3387-3391). The RNA polymerase β-subunit-coding gene (rpoB) (1) was used for the detection and identification of H. Pylori by specific PCR restriction analysis (PRA).

The predictability in the art: The art is highly predictable to treat a stress induced ulcer by using PPI or treat a bacterial caused ulcer by using an antibacterial compound. But is not predictable to treat an acid induced ulcer by using an antibacterial drugs nor can an ulcer caused by bacteria be treated by PPI.

Amount of guidance/working examples: On page 46 of the specification, applicant has example to treat acid. However, applicant has not guidance or examples for treating bacteria versions.

The breadth of the claims: The breadth of claims is drawn to preventing or treating gastrointestinal Illnesses, which included acid induced or bacteria ulcer.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treating microorganisms, one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted

that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claims 10, and 14, for treating gastrointestinal disease, have been enabled by the instant specification.

6. *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S.

1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 103(a) as being unpatentable over Senn-Bilfinger et al. US 6160119 or US 6197783 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in US 6,160,119 disclosed a fused dihydropyran compound useful for treatment of gastrointestinal diseases. See columns 1-2 and column 22, claim 1. Specific examples are described in columns 5-6, Table 1 and on column 24, claims 6-7. Senn-Bilfinger in US 6,197,783 disclosed a tetrahydroimidazonaphthyridine compound useful for treatment of gastrointestinal diseases. See columns 1-2 and columns 25-26, claim 1. Specific examples are described in columns 5-6, table 1 and on columns 27-28, claims 6-7.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxy compounds of Senn-Belfinger et al. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing

compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Sen-Bilfinger et al. as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

7. Claims 1-14 are rejected under 103(a) as being obvious over Grundler et al. (WO 98/54188), or Simon et al. WO 98/42707 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679.

Determination of the scope and content of the prior art (MPEP §2141.01)

Grundler disclosed a fused dihydropyran compound useful for treatment of gastrointestinal diseases on the pages 1-2, and page 26, claim 1. Specific examples are described in pages 6-7, table 1 and on page 28, clam 6-7. Simon generically disclosed a tetrahydroimidazonaphthyridine compound useful for treatment of gastrointenstinal diseases on the pages 1-2 and page 33, claim 1. Specific examples are described in pages 6-7, table 1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Grundler and Simon compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxy compounds of Grundler and Simon. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Grundler and Simon as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

8. Claims 1-14 are rejected under 103(a) as being obvious over Senn-Bilfinger et al. (WO 00/26217), in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger disclosed tetrahydroimidazonaphthyridine compound useful for treatment of gastrointenstinal diseases on the pages 1-5 and page 34-35, claim 1. Specific examples are described in pages 13-23, table 1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxy compounds of senn-Bilfinger. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Senn-Bilfinger as taught

by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

9. ***Claim Rejections - Obvious Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1,1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-8 of US 6,916,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in US 6,916,825 claimed analogous compounds useful for treatment of gastrointestinal diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that the instant claims are fully embraced by the prior art claims.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

The instant claims 1-14 are therefore fully embraced by the prior art claims 1-8.

10. *Claim Rejections - Obvious Double Patenting*

Claims 1-14 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-11 of US 6,384,048. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in US 6,384,048 claimed tetrahydroimidazonaphthyridine compound useful for treatment of gastrointestinal diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is that the instant claims are fully embraced by the issued claims 1-11 of the US 6,384,048, i.e. when R8 is hydrogen of the issued claims.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

There is no good reason why the issued scope should be given continuous exclusivity in the broad scope of the instant claims.

11. *Claim Rejections - Obvious Double Patenting*

Claims 1-14 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-10 of US 6,160,119 or the claims 1-14 of US 6,197,783 in views of Bundgaard (DE 4308095), Schulte and Aungst for reasons set forth in paragraph 6 above.

12. *Claim Rejections - Obvious Double Patenting*

Claims 1-14 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-13 of US 6,436,953 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in US 6,436,953 claimed tetrahydroimidazonaphthyridine compound useful for treatment of gastrointestinal diseases.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant

claims 5,8. The instant claims are therefore the prodrug of the hydroxyl-tetrahydroimidazonaphthyridine compounds of Senn-Belfinger et al. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the hydroxyl compound of Sen-Bilfinger et al. as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

13. ***Claim Rejections - Obvious Double Patenting***

Claims 1-9, 11, 13 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/182620 or claims 1-8 of copending Application No. 10/182654 or claims 1-15 of copending Application No. 10/103733 in view of Bundgaard et al. DE 4308095, Schulte et al. US 5432183, and Aungst US 4673679. Although

the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in copending application 10/182620, 10/103733, 10/182654 claimed fused dihydropyran and tetrahydroimidazonaphthyridine compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that Senn-Bilfinger compounds in the tables have R' substituted a hydroxyl whereas the instant claims have a radical from which a hydroxyl group is formed under physiological conditions, such as the methyl carboxylate, ethyl carboxylate etc. as recited in the instant claims 5,8. The instant claims are therefore the prodrug of the hydroxyl-tetrahydroimidazonaphthyridine compounds of Senn-Belfinger et al. The preparation of the prodrug for enhanced solubility, delivery, and other pharmacokinetics is well known in the pharmaceutical art. It is generally taught by Bundgaard on the page 1 and 3, table 2 and specifically shown for various hydroxyl containing compounds, as in DE 4308095 (see English abstract), Schulte (5432183, see column 2, lines 9-39) and Aungst (4673679, see columns 11-12, table 1) wherein the prodrug of hydroxymorphinan lacks the bitter taste of the parent compound and enhances its bioavailability (abstract).

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would have been motivated to prepare the prodrug of the copending hydroxy compound of Sen-Bilfinger et al. as taught by Bundgaard, DE 4308095, Schulte, US 5432183, and Aungst US 4673679 to arrive at the instant invention for enhanced delivery of the drug compounds.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. *Claim Rejections - Obvious Double Patenting*

Claims 1-9, 11, 13 are provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/485,514. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Senn-Bilfinger in copending application 10/485,514 claimed compounds and compositions in the claims 1-6 as the same structural core formula with subset of Markush elements as the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds are fully embraced each other.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

The claims of the instant application and copending application contain enormous amount of overlapping subject matter. The overlapping subject matter is the result of the mix and matching the Markush elements from the broad scope. Mix and matching of Markush elements are considered prima facia obvious.

This is provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

01/03/2006

NR

D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625